

§ 460.94

- (15) Otorhinolaryngology.
- (16) Plastic surgery.
- (17) Pharmacy consulting services.
- (18) Podiatry.
- (19) Psychiatry.
- (20) Pulmonary disease.
- (21) Radiology.
- (22) Rheumatology.
- (23) General surgery.
- (24) Thoracic and vascular surgery.
- (25) Urology.
- (l) Laboratory tests, x-rays and other diagnostic procedures.
- (m) Drugs and biologicals.
- (n) Prosthetics, orthotics, durable medical equipment, corrective vision devices, such as eyeglasses and lenses, hearing aids, dentures, and repair and maintenance of these items.
- (o) Acute inpatient care, including the following:
 - (1) Ambulance.
 - (2) Emergency room care and treatment room services.
 - (3) Semi-private room and board.
 - (4) General medical and nursing services.
 - (5) Medical surgical/intensive care/coronary care unit.
 - (6) Laboratory tests, x-rays and other diagnostic procedures.
 - (7) Drugs and biologicals.
 - (8) Blood and blood derivatives.
 - (9) Surgical care, including the use of anesthesia.
 - (10) Use of oxygen.
 - (11) Physical, occupational, respiratory therapies, and speech-language pathology services.
 - (12) Social services.
 - (p) Nursing facility care.
 - (1) Semi-private room and board.
 - (2) Physician and skilled nursing services.
 - (3) Custodial care.
 - (4) Personal care and assistance.
 - (5) Drugs and biologicals.
 - (6) Physical, occupational, recreational therapies, and speech-language pathology, if necessary.
 - (7) Social services.
 - (8) Medical supplies and appliances.
 - (q) Other services determined necessary by the multidisciplinary team to improve and maintain the participant's overall health status.

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§ 460.94 Required services for Medicare participants.

(a) Except for Medicare requirements that are waived for the PACE program, as specified in paragraph (b) of this section, the PACE benefit package for Medicare participants must include the following services:

(1) The scope of hospital insurance benefits described in part 409 of this chapter.

(2) The scope of supplemental medical insurance benefits described in part 410 of this chapter.

(b) *Waivers of Medicare coverage requirements.* The following Medicare requirements are waived for purposes of the PACE program and do not apply:

(1) The provisions of subpart F of part 409 of this chapter that limit coverage of institutional services.

(2) The provisions of subparts G and H of part 409 of this chapter, and parts 412 through 414 of this chapter that relate to payment for benefits.

(3) The provisions of subparts D and E of part 409 of this chapter that limit coverage of extended care services or home health services.

(4) The provisions of subpart D of part 409 of this chapter that impose a 3-day prior hospitalization requirement for coverage of extended care services.

(5) Sections 411.15(g) and (k) of this chapter that may prevent payment for PACE program services to PACE participants.

§ 460.96 Excluded services.

The following services are excluded from coverage under PACE:

(a) Any service that is not authorized by the multidisciplinary team, even if it is a required service, unless it is an emergency service.

(b) In an inpatient facility, private room and private duty nursing services (unless medically necessary), and non-medical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the multidisciplinary team as part of the participant's plan of care).

(c) Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part

of the body resulting from an accidental injury or for reconstruction following mastectomy.

(d) Experimental medical, surgical, or other health procedures.

(e) Services furnished outside of the United States, except as follows:

(1) In accordance with §§ 424.122 through 424.124 of this chapter.

(2) As permitted under the State's approved Medicaid plan.

§ 460.98 Service delivery.

(a) *Plan.* A PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year.

(b) *Provision of services.* (1) The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care.

(2) These services must be furnished in at least the PACE center, the home, and inpatient facilities.

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

(c) *Minimum services furnished at each PACE center.* At a minimum, the following services must be furnished at each PACE center:

(1) Primary care, including physician and nursing services.

(2) Social services.

(3) Restorative therapies, including physical therapy and occupational therapy.

(4) Personal care and supportive services.

(5) Nutritional counseling.

(6) Recreational therapy.

(7) Meals.

(d) *Center operation.* (1) A PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.

(2) A PACE organization must ensure accessible and adequate services to meet the needs of its participants. If necessary, a PACE organization must increase the number of PACE centers, staff, or other PACE services.

(3) If a PACE organization operates more than one center, each center must offer the full range of services and have sufficient staff to meet the needs of participants.

(e) *Center attendance.* The frequency of a participant's attendance at a center is determined by the multidisciplinary team, based on the needs and preferences of each participant.

§ 460.100 Emergency care.

(a) *Written plan.* A PACE organization must establish and maintain a written plan to handle emergency care. The plan must ensure that CMS, the State, and PACE participants are held harmless if the PACE organization does not pay for emergency services.

(b) *Emergency care.* Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or one of its contract providers, would cause risk of permanent damage to the participant's health. Emergency services include inpatient and outpatient services that meet the following requirements:

(1) Are furnished by a qualified emergency services provider, other than the PACE organization or one of its contract providers, either in or out of the PACE organization's service area.

(2) Are needed to evaluate or stabilize an emergency medical condition.

(c) An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(1) Serious jeopardy to the health of the participant.

(2) Serious impairment to bodily functions.

(3) Serious dysfunction of any bodily organ or part.

(d) *Explanation to participant.* The organization must ensure that the participant or caregiver, or both, understand when and how to get access to emergency services.

(e) *On-call providers.* The plan must provide for the following: